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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,188

10/15/2003

Edward T. Wei

7569

7590

07/13/2006

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EXAMINER

JONES, DAMERON LEVEST

ART UNIT PAPER NUMBER

1618

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/687,188	Applicant(s) WEI, EDWARD T.	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/20/06 and 4/19/06.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-23,25,26,28 and 30-33 is/are pending in the application.
 4a) Of the above claim(s) 17-22 is/are withdrawn from consideration.
 5) ☒ Claim(s) 1-5,7 and 11-15 is/are allowed.
 6) ☒ Claim(s) 8-10, 16, 23, 25, 26, 28, and 30-33 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/19/06 wherein claims 1, 5, 11, 12, 23, 26, 28, 30, and 31 are amended and claims 6, 24, 27, 29, 34, and 35 are canceled.

Note: Claims 1-5, 7-23, 25, 26, 28, and 30-33 are pending.

RESPONSE TO APPLICANT'S AMENDMENT

2. The Applicant's arguments and/or amendment filed 4/19/06 to the rejection of the claim made by the Examiner under 35 USC 112 have been fully considered and deemed persuasive-in-part for the reasons set forth below.

112 First Paragraph Rejection

The 112, first paragraph, rejection is WITHDRAWN because Applicant has canceled the respective claims.

112 Second Paragraph Rejection

All outstanding rejections, EXCEPT the following is WITHDRAWN because Applicant has amended the claims to overcome the 112, second paragraph, rejections.

The rejection of claims 8, 26, 28, and 30-33 under 35, USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 12/27/05 and those set forth below.

Applicant did not response to the Examiner's 112, second paragraph, rejections in the response filed 4/19/06.

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Once again, Applicant is reminded that the claims contain improper Markush terminology. The terms 'includes' and 'comprises' are open and Markush claims require closed terminology. Applicant is, once again, respectfully requested to review MPEP 803.02 which discloses acceptable Markush terminology. In addition, it is noted that if an independent claim contains open terminology (i.e., claim 26) and some of the dependent claims contain closed terminology, the claims are still deemed to contain improper terminology since it is not clear exactly how Applicant intended the claim to read.

WITHDRAWN CLAIMS

3. Claims 17-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

NEW GROUNDS OF REJECTIONS

101 Rejection (Use Claims)

4. Claims 9 and 10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

112 Second Paragraph Rejections

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9, 10, 16, 23, 25, 26, 28, and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9 and 10 provide for the use of the radioligand, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 16: The term "high affinity" is a relative term which renders the claim indefinite. The term "high affinity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 23 and 25: The claims as written are ambiguous because in independent claim 23, it is unclear for what reason the method is being used. For example, the claim reads, 'A method for using a radioactive ligand...', but does not identify the reason for the method. For example, if an application discloses 'A method of treating prostate tumors...', the reason (treating tumors) of why a product is being administered is identified.

Claims 23 and 25: The claims as written are ambiguous because independent claim 23 contains the phrase 'under conditions sufficient to permit specific binding...'. In particular, the claim does not set forth the specific conditions which are believed to be sufficient to permit specific binding.

Claims 26, 28, and 30-33: The claims are ambiguous because independent claim 26 discloses that 'the radiohalo moiety is covalently bound in the molecule', but does not disclose what it is bound to. Is it covalently bound to the alkylcarboxamide moiety or some other structure?

COMMENTS/NOTES

7. It is duly noted in the response filed 4/19/06 that Applicant asserted that the claims have been amended to the elected invention. However, review of the claims does not indicate that the pending claims have been limited to the SAME scope as that indicated as the allowable product by the Examiner. In particular, according to MPEP 821.04 which discloses the rejoinder of claims, it is disclosed that 'If Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined'. Thus, Applicant is respectfully requested to limit the claims (products and methods) as set forth the restriction: elected Group II is directed to radioligands wherein the alkyl moiety **is** a cyclohexane, not alkyl moieties **comprising** cyclohexane (i.e., see claim 26) and compositions comprising a branched chain N-radiohalo-substituted-aryl alkylcarboxamide wherein the alkyl includes

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cyclohexane and others (i.e., see claim 17). Furthermore, Applicant is reminded that the terms 'including' and 'comprising' indicates that only cyclohexane or some structure containing a cyclohexane may be present. In other words, the phrase 'comprising cyclohexane' and 'including cyclohexane' deviate from the elected invention. Also, it should be noted that such terms ('including' and 'comprising') allow for unnamed ingredients/components/structures to be present in the product/methods.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

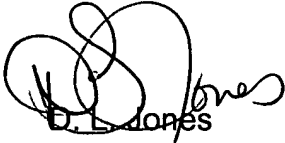
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
Art Unit 1618

July 7, 2006